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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WEBER, JON P

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/023,275	Applicant(s) STEINERT ET AL.	
	Examiner Jon P Weber, Ph.D.	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 7-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/16/02</u> . | 6) <input type="checkbox"/> Other: _____ |

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Election/Restrictions

Applicant's election of Group I, claims 1-4 and 6, in the Paper filed 22 December 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a)). Claims 5 and 7-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. The requirement is deemed proper and is therefore made FINAL. It is suggested that the non-elected claims be canceled in response to this Office action to expedite prosecution.

Claim Objections

Claim 4 is objected to because of the following informalities: there is a box symbol after cystatin on line 4. Based on the disclosure at page 3, line 3 and elsewhere, it would appear that this should read "cystatin- α ". Several of the non-elected claims also have a box symbol. Appropriate correction is required.

Claim 4 is grammatically awkward. The "and" should be between the penultimate and the ultimate members of the group.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites “delivery agent” which is inconsistent with the art accepted meaning of a delivery agent. It is thought that the components in the grouping are additional active agents co-delivered in the SLV with transglutaminase I.

Claim 4 recites “members of the small proline rich family” which is vague and indefinite because the metes and bounds of members encompassed by the claims is unclear. How they differ from specifically identified small proline rich proteins already specifically identified in the claim is also unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lai et al. (1997).

Lai et al. (1997) disclose combining tissue transglutaminase (appears to be the same enzyme herein called TGA-I) with various synthetic lipid compositions (Table I) and observing the effect of the lipids on the activity of the enzyme.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable Bernard et al. (US 6,274,364).

Bernard et al. (US 6,274,364) disclose cosmetic compositions of vesicular dispersions of the ionic and/or anionic type (col 7, lines 47-48) for treating, *inter alia*, ichthyosis (col 8, line 8) comprising transglutaminase as an at least one protease activator in combination with subject polypeptide, a cathepsin L-type cysteine protease (col 7, lines 17-20). Bernard et al. (US 6,274,364) does not exemplify this particular combination but strongly suggests this combination as a reasonable composition for skin treatment.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising transglutaminase and SLV.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cevc (US 6,165,500).

Cevc (US 6,165,500) discloses synthetic transfersome vesicles (col5, line 51 to col 6, line 3; col 4, lines 37-46) which may contain any of a large number of possible active agents (col 20, lines 1-3) including, *inter alia*, transglutaminase (col 45, line 26). Cevc (US 6,165,500) does not

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exemplify this particular combination but strongly suggests this combination as a reasonable composition for transporting active agents through the skin.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising transglutaminase and SLV.

Claim 1-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai et al. (1997), Bernard et al. (US 6,274,364), Cevc (US 6,165,500) in view of Green et al. (US 5,525,336), Steinert et al. (1998) and Crawford et al. (WO 9322281).

The teachings of Lai et al. (1997), Bernard et al. (US 6,274,364), Cevc (US 6,165,500) have been discussed above. None of Lai et al. (1997), Bernard et al. (US 6,274,364), Cevc (US 6,165,500) teach adding additional agents such as in instant claims 2-4 or using the specific lipid in claim 6.

Green et al. (US 5,525,336) disclose making cosmetic compositions comprising transglutaminase and a wide range of skin treating additives such as involucrin, loricin, cystatin, fibers, pigments, etc. in the form of emulsions, with surfactants and emollients.

Steinert et al. (1998) disclose, Fig. 5, a model of the skin showing how the various skin proteins are crosslinked by transglutaminase.

Crawford et al. (WO 9322281) teaches how to make synthetic ceramides such as the instant lipid-Z (encompassed by the disclosure) for use in cosmetic compositions.

A person of ordinary skill in the art at the time the invention was made would have been motivated to combine transglutaminase in a synthetic vesicle as disclosed or suggested by Lai et al. (1997), Bernard et al. (US 6,274,364), Cevc (US 6,165,500) with known skin protein

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substrates as suggested by Green et al. (US 5,525,336) and Steinert et al. (1998) or to use the specific lipid-z in the vesicles as suggested by Crawford et al. (WO 9322281) because these are all cosmetic skin treatments and Green et al. (US 5,525,336) has indicated that transglutaminase should be combined with additional protein substrates and skin active agents. The selection of a particular lipid-z from among the synthetic ceramides suitable for cosmetic compositions as disclosed by Crawford et al. (WO 9322281) is an arbitrary matter of experimental design choice.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising transglutaminase and SLV with additional substrates and active agents or specific lipids.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 571-272-0925. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

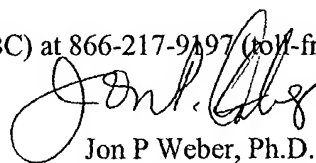
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jon P Weber, Ph.D.
Primary Examiner
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JPW
27 February 2004